

The iSupport-PD Study

Evaluating a website for care partners of people with Parkinson's with changes to memory, thinking or behaviour

Participant Information Sheet

Researcher: Professor Annette Hand

What and who is the research about?

Unpaid care partners may provide care or support for a partner, friend, or family member with Parkinson's. This care or support may include emotional or practical support (e.g. driving to appointments) as well as day to day living activities (such as managing medications or helping with mealtimes). Memory, thinking and behavioural issues, such as

You are invited to take part in a research study. To help you decide if you would like to take part, it is important that you understand why the study is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information. You may like to discuss it with others, but it is up to you to decide if you want to take part.

forgetting things, problems concentrating, repetitive activities or finding it difficult to make

How do I sign up?

If after reading the information below, you want to sign up/find out more: Complete an online form to tell us that you are interested in taking part:

[Get involved | iSupportPD \(northumbria.ac.uk\)](https://www.northumbria.ac.uk/iSupportPD)

decisions are common symptoms experienced by people with Parkinson's. Currently there is

a lack of support for care partners of people with Parkinson's and the memory, thinking and behavioural changes they may experience.

We are adapting an existing accredited digital support tool to meet these specific needs of care partners. We have worked with care partners and experts to develop a website to support care partners of people with Parkinson's with changes to memory and thinking.

This research trial aims to test and evaluate our website, to ensure it is engaging and relevant to all care partners.

Who can take part in the research?

Adult unpaid care partner, aged 18 years and over, living in the UK who provide support for someone who:

1. Has a confirmed diagnosis of Parkinson's; and
2. You think may have problems with memory, thinking or behaviour.

You don't need to be living with the person with Parkinson's to take part. The person you provide care or support for does not need to have had an assessment with a health professional for memory or thinking problems.

Do I have to take part?

No, it is up to you whether you take part or not. If you decide to take part, we will ask you to complete a short form that shows you have agreed to take part.

What will I need to do?

If you are interested in taking part, we ask you to let us know by completing an online expression of interest form. The form will ask you questions about you and the person you provide care or support for to check that the study is right for you.

It is important that a diverse range of care partners take part in this study, therefore we will try and select people who are different from each other. To enable this, we will ask you to provide us with some background information about you as a care partner. If you are not eligible to take part, we will contact you to let you know.

What will happen if I take part?

If you choose to take part in the study, we will ask you to complete a consent form and some initial questionnaires. This will take no more than 30 minutes. You will then be put into one of two groups by chance (randomly). There is a 50% chance of being in either group. The two groups are:

- **The website group.** People in this group will be given access to the website and can access this whenever they want, and view as much, or as little content as they like, at a time that is convenient to them. People in this group will have access to website for 12 months.
- **Control group.** People in this group will continue with their normal support and will not have access to website during the study. People in this group will be given access to website at the end of the study.

People in both groups will be asked to complete some further questionnaires at 3 months, 6 months and finally at 12 months. The questionnaires are on-line and should take no longer than 30 minutes to complete.

People in both groups will also ask you if you would be interested in taking part in an optional on-line interview. The interview would last no longer than one hour and would be arranged on a date and time to suit you. For people in the website group the interview will explore your experiences of using the website. For people in the Control group the interview will explore your role as a care partner, and the usual support you receive in this role.

Are there any benefits in my taking part?

You may get some direct benefit from taking part in this study, whichever group you are put in. If you are in the website group, the content and activities may be useful to you as a care partner. If you are in the Control group, you will also be given access to the website at the end of the study. All study participants will receive a £10 gift voucher at the end of the study as a thank you for taking part.

Are there any risks involved?

We do not anticipate that there are any risks involved in taking part. Some of the questions we need to ask will focus on your mental health and on your relationship with the person with Parkinson's. There is a possibility that some people may find these questions upsetting. If this happens, we can give you details of the Parkinson's UK and Mind charities where you can get advice and support if needed. You are free to refuse to answer any questions which you do not wish to answer.

What data will be collected?

Data about yourself and the person with Parkinson's will be collected to help us make sure we include a wide range of people in this study. This may include age, gender, and ethnicity. You do not have to give this information if you do not want to.

We will collect questionnaire data. The questionnaires will explore your mood, your caring role and any impact it may have on you, how resilient you are, the quality of your relationship with the person you care for and your quality of life.

If you are randomised to access the website we will monitor how much, and how often you use the website. If you are invited to take part in an interview, we will ask you about your views and experiences of using the website, or what support you have in your role.

What happens to the data being collected?

All data, including the questionnaires, the typed transcripts from your interview and your consent form will be stored on a university password protected computer. All electronic data including the recording from your interview, will be stored on the University U drive, which is password protected. All data will be stored in accordance with University guidelines and the Data Protection Act (2018).

We will type code numbers instead of your name, so no-one can find out who you are. Interviews will be recorded using a recording device and the recording will then be stored on a university password-protected computer and then deleted from the recording device. It will be typed up by a member of the research team. They will keep everything they hear private and will type code numbers instead of your name, so no-one can find out who you are. We will delete all recordings as soon as the study team have checked and are happy with the quality of the written transcript.

We will review what you have told us and put it together with what other people tell us. Your personal details that could identify you and your associated code number will be stored separately from the written transcript and recordings. All this information will be stored securely on computers at the Northumbria University and will only be accessible by the research team. We will delete the personal details that match your code number at the end of the study (November 2025) when we have finished our analysis.

You will be asked if you are happy for your questionnaire data, website usage data and the transcript of your interview, with all personal details that could identify you removed, to be shared with people outside of the research team for research and education purposes. This part of the research is optional.

Will my participation be confidential?

Your participation and the information we collect about you will be kept strictly confidential and will only be shared with the research team. We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require

access to the information we collect about you to check that we are carrying out the study correctly. These people have a duty to keep your information strictly confidential. The only time we would not be able to keep something confidential is if we had serious concerns about your safety or the safety of the person you care for. We would share this information with the most appropriate sources of further support and advice. We would try to get your permission before doing this but would still proceed without it if necessary.

What happens if I change my mind?

You have the right to change your mind and withdraw from the study at any time without giving a reason. If you decide to withdraw, any data you have provided will be deleted if you request this, unless it has already been used anonymously in the analysis or results of the study.

What will happen to the results of the study?

The results of the study will be written up as a report for the National Institute for Health and Care Research and will be published in scientific journals and presented at research conferences. We may use direct quotes from the interviews but **none** of your personal details that could identify you will be used (e.g. your name).

Who is Organising and Funding the Study?

Northumbria University and the University of Southampton are organising the study. The study has been funded by the National Institute for Health and Care Research (NIHR), Research for Social Care.

Who has reviewed this study?

The research project, submission reference 2024-0217-6596 has been approved in Northumbria University's Ethics Online system. The project has been reviewed in order to safeguard your interests, and we have been granted approval to conduct the study.

What are my rights as a participant in this study?

Each participant has a right of access to a copy of the information included in their personal data by submitting a ([Subject Access Request](#)); a right in certain circumstances to have inaccurate personal data rectified; and a right to object to decisions being taken by automated means.

Where can I get more information?

If you have any questions about this study, please contact:

Professor Annette Hand, Nursing, Midwifery and Health, Faculty of Health and Life Sciences, Northumbria University, Coach Lane Campus, Coach Lane, Tyne and Wear NE1 8ST Email: isupportpd@northumbria.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher (isupportpd@northumbria.ac.uk) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Duncan James (dp.officer@northumbria.ac.uk), the Records and Information Officer at Northumbria University. As study Sponsor, Northumbria University has insurance to cover this research study, which includes compensation cover in the event that any claims arise from participation in the study.

Thank you

Thank you for taking the time to read the information sheet and considering taking part in this study.

Data Protection Privacy Notice:

1. Data Controller

Data Controller: University of Northumbria at Newcastle
Registration Number: Z7674926

2. Introduction

Some of our research will involve the collection of personal data (information that can be used to identify someone) or special category data (personal data which relates to your ethnicity, sex life or sexual orientation, health or disability, biometric or genetic data, religious or philosophical beliefs, political opinions or trade union membership). The General Data Protection Regulation (GDPR) and the Data Protection Act 2018 (DPA), supported by our own policies and procedures, govern the conduct of our research and require us to inform research participants as to how their data will be processed when they agree to participate in our research projects. This privacy notice supplements the participant information sheets or consent form you will have received when you agreed to participate in a research study or project run by staff or students working on behalf of the University.

3. Purpose and lawful basis of the processing

When we collect personal information from you, a Participant Information Sheet will explain what information we are using and how we are going to use it and the lawful basis under which the data is processed.

As a UK Higher Education institute, the University has an obligation to advance knowledge and education through its teaching and research activities. In order to fulfil this obligation, staff and student researchers at the University have a public interest to collect and analyse personal data to achieve their research aims.

All of our research projects will have different requirements for processing of personal data and the type of data collected will vary significantly depending on the objectives of the project. All of our researchers require ethical approval to process personal data as part of their research. This ensures that they only ever collect data that is required to achieve the outcome of their research. Data collected by students may be processed for assessment purposes and viewed by their supervisors or other staff members should there be a requirement as part of our Research Misconduct Procedures.

The GDPR states that we must have a lawful basis for processing personal data. For most projects (excluding those related to health or social care) the processing of personal data for research purposes will be under one of the following:

- Where the University processes personal data, in most cases, we do so under article 6(1)(e) GDPR, which permits processing that is 'necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'.
- Where the University processes special categories of personal data, in most cases, we do so under Article 9(2)(j) GDPR, which permits processing that is necessary for scientific or historical research purposes, providing we have appropriate security safeguards in place.

Neither of the above lawful basis require us to seek your consent to process data, because the processing is deemed to be part of our public task. Consent as a lawful basis to process personal data would often not be compatible with research objective because the withdrawal of consent to process the data could have an adverse impact on the research outcome. Whilst you may not be asked to consent to processing of your data, you will be asked to consent to participate in the project, but this includes your understanding that participation required the processing of data under the 'public task' lawful basis. You can step off the project at any time, but we are not obliged to cease processing any of data collected from you whilst you were participating.

4. Health and Social Care Projects

Where the university processes personal data or special category data held within medical records, we will seek your explicit consent to access this data. Once you have provided this consent, the processing of this information will be under the provisions of Article 6(1)(e) and Article 9(2)(J). Data relating to criminal convictions and offences Projects that require researchers to process data relating to processing criminal convictions and offences personal data will be under Article 9(2)(j) and in accordance with the DPA 2018, we will ensure that 'appropriate safeguards' are in place.

5. Where does data come from?

All of our research projects will have different requirements for processing of personal data. This means that the type of data collected and the source of the data may vary significantly depending on the objectives of the project. Some projects may require data to be collected directly from you, whilst some may require us to obtain data from a third party who we are working with. For example, NHS Trusts, Councils, Charities, Schools or any funders or partners in our research.

6. Third party data sharing

Where our research involves collaboration with other institutions or organisations, we may be required to share identifiable information with those third parties. You will be notified of the presence of such third parties within a

participant information sheet. The sharing of such data will always be limited to what is “necessary” for achieving the proposed outcomes of the project and will only be via secure mechanisms with appropriate safeguards. Our research may be audited by external bodies and access to data by these parties may be required. Safeguards will be used to ensure that audits are conducted in a secure and confidential manner.

6. Publishing information about you

As part of our public task, we are required to publish research outcomes and to make available research data sets for future analysis. Your data will be anonymised before any publication, or transfer to a dataset - unless you have previously given your explicit consent for it to remain identifiable for publication. Data would remain identifiable where it is required to meet a specific project requirement and only where you have had that requirement communicated to you in the Participant Information sheet in order to gain your consent to do so. You will be asked for consent to publish any images or video footage of you if as a result of your participation you are asked to further participate in promotional materials. You may withdraw this consent at any time, but where the materials have been published or disseminated, we may not be in a position to remove such images.

7. How do we store your data?

Because our research projects have different requirements for processing of personal data, each project will have its own specific data management plan which is approved by the University Ethics Committee. A data management plan will always ensure that the project is taking the most appropriate steps to ensure the security of personal data used for research purposes. Wherever possible, projects will use anonymisation or pseudonymisation at the earliest opportunity to ensure that data only remains identifiable for a minimum amount of time. Technical security measures will be proportional to the type of data being processed and projects processing special category data will always have the highest level of security available. As well as the technical and physical aspects of security, the University has training, policies and procedures in place that staff follow at all times when processing data.

8. Your Rights (including under GDPR)

GDPR provides you with a number of rights in relation to processing your personal information. You have the right to:

- Request access (to a copy) of the personal information held about you.
- Request that we correct inaccurate or incomplete data.
- Ask to have certain data ‘erased’ by us.
- Request that we restrict certain processing of your personal data.
- Request that any data you submitted to us electronically be returned to you or passed to a third party as a data file.

Due to the nature of research related processing, in some cases, there may be specific exemptions as to why we are not required to comply with some of the above rights, such as when implementing your rights would preclude or prejudice the research outcomes for which data were collected. This will be communicated to you in the Participant Information Sheet. Where it is deemed necessary to refuse any request from you to exercise your rights, we will explain the reasons for this within one month. You have the right to complain about our decision to the Information Commissioner. If data collected about you has been anonymised, it will not be possible to identify you or access your personal information.

9. How long data will be retained

Wherever possible, researchers will use anonymisation or pseudonymisation to at the earliest opportunity to conceal or protect your identity, unless the nature of the research prohibits this. Where the research requires the data to remain identifiable, we will store your data and associated consent forms for the length of the project, and for a specified period following the end of the project. This period will be in line the research section of our retention schedule and explained to you within the participant information sheet provided. Where your data has been anonymised and archived in a research data set, this data will remain in our research data repository for as long as publication requirements permit.

10. Data Protection Officer

The Data Protection Officer for Northumbria University is Duncan James.

If you have any questions which you feel have not been covered by this Privacy Notice, or if you have concerns or a complaint in relation to the University processing your personal data, please do not hesitate to email us at: dp.officer@northumbria.ac.uk. If your request is urgent, please call +44 (0)191 243 7357

11. Lodging a Complaint with the Information Commissioners Office

Should you be dissatisfied with the University’s processing of your personal data, you have the right to complain to the Information Commissioner’s. For more information see Information Commissioner’s web site.